

AMENDMENTS TO THE CLAIMS

Please amend Claims 9, 13, 21, and 34. Claims 10, 11, 12, 14, 15, 22, 23, 25, 27, 29, 30, 31, 32, 33, 35, and 36 remain as previously pending.

1. – 8. (Cancelled)

9. (Currently Amended) A method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising:

inserting a tapered tip of a flexible trocar and a distal end of an axially elongate tube into an incision into a thoracic cavity of a mammalian patient, wherein the flexible trocar is pre-inserted through a drainage lumen of a bidirectional, non-removable, pressure-operated valve attached to a proximal end of the axially elongate tube and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube;

selectively bending a region near the distal tip of the axially elongate tube while advancing the axially elongate tube into the thoracic cavity, wherein the bending steers the axially elongate tube into the thoracic cavity during insertion;

removing the flexible trocar through the valve from the drainage lumen of the axially elongate tube and the drainage lumen of the valve; and

selectively opening or closing the valve to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube.

10. (Original) The method of Claim 9 wherein said bending of the axially elongate tube is controlled from the proximal end of said axially elongate tube whereby tortuous anatomy can be navigated.

11. (Original) The method of Claim 9 wherein said bending of said axially elongate tube is caused by retraction of a control rod.

12. (Previously Presented) The method of Claim 9 wherein said bending of said axially elongate tube is caused by electrical activation of a plurality of shape-memory actuators acting in opposition, wherein one actuator is enabled simultaneously with the opposing actuators not being activated.

13. (Currently Amended) The method of Claim 9 wherein the step of selectively bending a region near the distal tip of the axially elongate tube is replaced by the steps of:

- inserting a hollow needle into the thoracic cavity;
- inserting a guidewire through the hollow needle into the thoracic cavity;
- removing the hollow needle following placement of the guidewire;
- advancing the chest drainage tube, comprising a flexible, trocar, further comprising a tapered distal tip and a guidewire lumen extending within the trocar, the length of the trocar, into the thoracic cavity over the guidewire; and
- removing the trocar.

14. (Original) The method of Claim 13 wherein said chest drainage tube is pre-mounted to said trocar.

15. (Original) The method of Claim 13 wherein said chest drainage tube is subsequently fixed in position relative to the opening in the chest wall.

16. – 20. (Cancelled)

21. (Currently Amended) A method of draining of fluid, air and contaminants from a patient's thoracic cavity comprising:

- inserting a hollow needle into an incision into the thoracic cavity of a patient;

- inserting a guidewire through the hollow needle into the thoracic cavity;
- removing the hollow needle after inserting the guidewire;

- pre-attaching a non-removable, bidirectional valve, further comprising a drainage lumen and a valve control lumen, to the proximal end of an axially elongate tube, wherein the axially elongate tube comprises a proximal end, a distal end, and a drainage lumen extending substantially the axial length of the axially elongate tube;

- inserting a flexible trocar comprising a tapered distal tip, and a guidewire lumen extending the length of the flexible trocar, within the trocar, through a drainage lumen of the valve, into the proximal end of the axially elongate tube and into the drainage lumen of the axially elongate tube until the tapered distal tip extends beyond the distal end of the axially elongate tube;

inserting a distal end of the axially elongate tube, comprising the pre-inserted flexible trocar and pre-attached, pressure-operated, bidirectional valve, over the guidewire and through the incision into the thoracic cavity of the patient, wherein the distal end of the axially elongate tube is advanced into the thoracic cavity of the patient;

removing the flexible trocar from the drainage lumen of the axially elongate tube and from the drainage lumen of the valve;

selectively opening or closing the drainage lumen of the valve, to control the influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube; and

removing the guidewire after inserting the axially elongate tube.

22. (Previously Presented) The method of Claim 21 further comprising selectively bending a region of increased flexibility near the distal tip of the axially elongate tube while advancing the tube into the chest cavity.

23. (Previously Presented) The method of Claim 21 wherein the axially elongate tube further comprises a sideport, operably connected to the drainage lumen, wherein said sideport is located near the distal end of the axially elongate tube.

24. (Canceled)

25. (Previously Presented) The method of Claim 21 wherein the valve is pre-attached to the axially elongate tube near the proximal end of the axially elongate tube, prior to removal of the axially elongate tube from a package.

26. (Canceled)

27. (Previously Presented) The method of Claim 21 further comprising the step of advancing an extracorporeal fixation device distally along the axially elongate tube so that the extracorporeal fixation device is adjacent the thoracic wall of the patient and then locking the extracorporeal fixation device to prevent axial movement of the extracorporeal fixation device along the axially elongate tube.

28. (Canceled)

29. (Previously Presented) The method of Claim 21 further comprising the step of activating an intracorporeal fixation device, said intracorporeal fixation device being affixed to the axially elongate tube.

30. (Previously Presented) The method of Claim 29, wherein the step of activating the intracorporeal fixation device comprises inflating a balloon through a balloon inflation port located substantially near the proximal end of the axially elongate tube.

31. (Previously Presented) The method of Claim 21, wherein the step of selectively opening the valve comprises drawing a vacuum within the valve enabling lumen, said valve enabling lumen being operably separated and not connected to the drainage lumen of the valve, to open the valve.

32. (Previously Presented) The method of Claim 31, wherein the step of selectively closing the valve comprises removing a vacuum from within a valve enabling lumen so that an open celled foam can expand to close the valve.

33. (Previously Presented) The method of Claim 21 wherein the valve is a normally closed valve.

34. (Currently Amended) A method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising:

inserting a chest drainage apparatus into a thoracic cavity of a mammalian patient, wherein the chest drainage apparatus comprises an axially elongate tube with a pre-inserted flexible trocar having a tapered distal tip, further wherein the flexible trocar is pre-inserted through a non-removable, pressure-operated, bidirectional valve, attached to a proximal end of the axially elongate tube, and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube;

advancing the chest drainage apparatus to its target location within the thoracic cavity;

removing the flexible trocar from the drainage lumen of the valve and the axially elongate tube; and

selectively opening or closing the valve to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube.

35. (Previously Presented) The method of Claim 21 further comprising the step of activating an internal fixation device, said internal fixation device being pre-

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attached to the axially elongate tube, following placement of the distal end of the axially elongate tube within the thoracic cavity.

36. (Previously Presented) The method of Claim 21 further comprising the step of activating an internal fixation device, said internal fixation device comprising a balloon which is pre-attached to the axially elongate tube, the activation step being accomplished by application of fluid pressure at the proximal end of the axially elongate tube, said fluid pressure causing inflation of the balloon.

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SUMMARY OF INTERVIEW

On Tuesday 7 November 2006, an Applicant, Jay A. Lenker, was extended the courtesy of a telephone interview with the Examiner. A summary of the interview follows:

- There were no exhibits presented at the interview.
- During that interview, Claim 9 was discussed in detail. Bruce '409 was the prior art cited primarily against Claim 9 and that prior art was reviewed.
- During the interview, an amendment to Claim 9, stating that the valve be pressure operated, was proposed and reviewed.
- Principal arguments pertaining to Claim 9 were directed toward the lack of prior art which discloses a steering or deflection in the prior art as part of the insertion process for a chest drainage tube since chest drainage tubes are placed either during open surgery or percutaneously with the aid of a rigid, sharp trocar and a virtually straight, but somewhat dangerous, approach into the thoracic cavity. Additional arguments pertaining to Claim 13 and 21 were directed toward the lack of prior art which discloses inserting a chest tube over a guidewire.

Results of Interview

Agreement was reached as to the general scope of the Claim amendments to distinguish over the cited prior art. The Examiner instructed the Applicant to file the response to the final office action as a Request for Continued Examination (RCE).